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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/892,407	07/15/97	KEITH	J 5238-D1V

HM11/1123

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EXAMINER	
MERTZ,P	
ART UNIT	**PAPER NUMBER**
1646	7

DATE MAILED: 11/23/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☑ Responsive to communication(s) filed on 8-13-98

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☑ Claim(s) 1-5, 7-27 is/are pending in the application.

Of the above, claim(s) 1-5, 8-26 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☑ Claim(s) 1-2, 7, 27 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☑ Notice of Reference Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of the species of claim 7 (antibiotic induced diarrheal diseases) in Paper No.6 (8/13/98) is acknowledged. The traversal is on the ground(s) that the restriction is improper since the Examiner has required election of a species among the species in claims 3 to 26 but claim 2 is generic to claims 3 to 5 and 7 to 26. This argument is not found persuasive because claims 1-2, 7 and 27 will be examined in response to Applicants election of species.

The diseases recited in claims 2, 3-5 and 7-26 comprise substantially different diseases because they have totally different pathologies and modes of treatment. They have therefore acquired a separate status in the art and the required searches would not overlap. The only feature in common in the instant inventions is "a method of treating an inflammatory disorder", which does not constitute the special technical feature lacking from the prior art because this method can be used with a composition other than the instant products such as IL-10 or IL-4. Distinctness is further shown because each of these disorders in each method can be treated with physically, chemically and biologically distinct products, which if patentable would support separate patents. Furthermore, separate search terms would be required for searching the literature, eg. a search of the literature for an association of arthritis with IL-11 would not necessarily reveal art for an association of IL-11 with gingivitis. Similarly, a search of the literature for an association of AIDS with IL-11 would not

necessarily reveal art for an association of IL-11 with asthma which searches are extensive requiring separate searches which would be unduly burdensome.

The election of species as delineated in the restriction requirement (Paper No. 4, 3/26/98) is still deemed proper.

2. Claims 3-5 and 8-27 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected species of invention.

Specification

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. It is suggested that the title be amended to recite a method of using IL-11 for treating antibiotic induced diarrhoea.

4. Applicants are advised of the following informality:

On page 8, lines 20-22, the old address of ATCC in Rockville, MD is disclosed. The new address is ATCC, 10801 University Boulevard, Manassas, VA 20110-2209.

Appropriate correction in the specification is required.

Claim Rejections - 35 USC § 112

5. Claims 1-2, 7 and 26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for treating antibiotic induced diarrheal diseases by organisms with IL-11, does not reasonably provide enablement for a method for treating all inflammatory disorders with IL-11. The specification does not enable any person skilled in the art

to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The specification discloses the effect of IL-11 on *Clostridium difficile* toxin A-mediated secretion (page 13, Example 2, lines 1-23) and the inhibitory activity of IL-11 with respect to treating antibiotic induced diarrheal diseases. However, the claims recite "treating an inflammatory disorder" which encompasses all conditions resulting from immune system stimulation. The instant specification is non-enabling for a method for stimulating disparate inflammatory disorders in the absence of support to accomplish a specific purpose by administration of IL-11. The recitation of the term "inflammatory disorders" in claim 1 embraces allergies, rhinitis and conjunctivitis. However, with respect to claim 2, AIDS is not an inflammatory disorder but a deficiency in the immune system. Furthermore, rheumatoid arthritis and multiple sclerosis are autoimmune diseases. Therefore, it is inconceivable that administration of IL-11 would produce opposing effects in a patient with AIDS and in a patient with rheumatoid arthritis and multiple sclerosis. Gingivitis is a bacterial disease, while tumor metastases is not an inflammatory disorder. Diabetes is caused by both an inherited defect as well as an environmental component. The ability of IL-11 to treat all these disparate disorders involving the immune system or hematopoietic system or not involving such would not be an enabled paradigm. IL-11 could not be administered with a predictable prognosis using the specification as guidance because the specification provides no examples nor is an enabling mechanism disclosed using IL-11 commensurate with the scope of the claims. In the absence of such a disclosure a skilled

artisan would be unable to practice the methods embraced by the claims without undue experimentation.

6. Claims 2 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2 and 7 are vague and indefinite because they recite "antibiotic induced diarrheal diseases (*Clostridium difficile*)". It is unclear if the diarrheal disease is caused by *Clostridium difficile*. It is suggested that the claims be amended to recite "antibiotic induced diarrheal diseases".

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7a. Claims 1, 2 and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Yang et al. (U.S. Patent No. 5,700,664).

Yang et al. teach a method of treating a disorder of the immune system, inflammation being an immune disorder, (column 11, lines 63-67; column 12, lines 1-15) comprising administering to

a subject an amount of IL-11. Yang also teaches that IL-11 may be employed in therapies for cancer (tumor metastases) and other pathological states resulting from disease such as bacterial infections, gingivitis being a bacterial infection of the gingiva in the mouth cavity (column 12, lines 1-7). Therefore, Yang et al. teach all of the process steps and material compositions of claims 1-2 and 27, including the dosage of IL-11 administered which is between 1 and 1000 μg/kg body weight (column 12, lines 41-46), and therefore anticipates claims 1-2 and 27.

7b. Claims 1, 2 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Bennett et al. (U.S. Patent No. 5,215,895).

Bennett et al. teach a method of treating a disorder of the immune system, inflammation being an inflammatory disorder (column 3, lines 15-18) comprising administering to a subject an amount of IL-11. Bennett also teaches that IL-11 may be employed in therapies for cancer i.e. tumor metastases (column 3, lines 27-32). Therefore, Bennett et al. teach all of the process steps and material compositions of claims 1-2 and 27, including the dosage of IL-11 administered which is between 1 and 1000 μg/kg body weight (column 11, lines 56-61), and therefore anticipates claims 1-2 and 27.

7c. Claims 1 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Keith et al. (1994).

Keith et al. teach a method of treating a disorder of the immune system, inflammatory bowel disease (lines 1-7) comprising administering to a subject an amount of IL-11. Therefore, Keith et al. teach all of the process steps and material compositions of claims 1 and 27, including the dosage of

PM 11/10/98 IL-11 administered which is 1 mg/kg body weight (lines 11-13 ~~12-22~~; and therefore anticipates claims 1 and 27.

7d. Claims 1 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Keith et al. (1995).

Keith et al. teach a method of treating a disorder of the immune system, inflammatory bowel disease (lines 1-5) comprising administering to a subject an amount of IL-11. Therefore, Keith et al. teach all of the process steps and material compositions of claim 1 and therefore anticipates claim 1.

Conclusion

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 8:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached on (703) 308-2731.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Prema Mertz

Prema Mertz Ph.D.
Patent Examiner
Group 1646
November 10, 1998